Federation of Chiropractic Licensing Boards

MODEL FRAMEWORK

UNIFORM EVALUATIVE PROCESS FOR TREATMENTS & DEVICES

OVERVIEW

In the spring of 2008, the Federation of Chiropractic Licensing Boards empaneled a special task force **to develop a model for a uniform review process** that chiropractic regulatory boards could utilize to guide their evaluations of treatments and devices.

Recognizing that regulatory boards are often asked by licensees, entrepreneurs, and those in the business of providing postgraduate education whether certain treatments or devices may be legally used in a jurisdiction, the task force sought to design a series of investigatory questions that could serve as a uniform springboard for a board's review process. The framework proposed here appreciates that all regulatory boards' primary function is to protect the public and consumers of chiropractic health care services. This model has been designed to expand a board's evaluation and also to provide some guidance and uniformity to its decision-making process. It is fully expected that a board would pursue additional and relevant questions that might arise in the course of conducting a careful review.

The task force also noted that the board may come to a variety of conclusions after studying a request regarding a treatment or device. It might determine that the concept falls within any one of the following categories, or other categories not listed herein:

- Within the existing chiropractic scope of practice
- Outside the chiropractic scope of practice
- More appropriately within the scope of another regulated profession
- Has the potential to harm the public and should therefore be subject to certain restrictions or banned altogether
- Represents possible innovation for the profession and should be allowed, perhaps subject to certain restrictions or guidelines

Following receipt of a request by the proponent for a treatment or device, a board might elect to initiate a detailed investigation, which includes soliciting additional information from the proponent, seeking input from legal counsel, surveying other boards, utilizing outside resources, or it may determine that sufficient information is available to make an immediate determination. Further, the board may decide that it will inform its regulatory stakeholders on a broader scale by way of guidance or advisory documents, or initiate new or modified regulatory language.

The model framework outlined here is designed to support the hard work of the Federation's member boards, and to assist them by providing a fair and uniform process to review requests for guidance by regulation's many important stakeholders.

The assessment model is divided into eight sections:

1. Scope of Practice Issues
2. Safety & Effectiveness
3. Recognition / Educational Settings
4. Lawful Use of Devices, Foods and Dietary Supplements
5. Publication / Marketing Information
6. Competency Assessment
7. Financial Arrangements
8. Special Considerations for Experimental Treatments and Devices

A board may gather the information on its own, or may initially provide the tool to the proponent of the treatment or device to supply as much detailed information as possible for the regulatory agency. In conjunction with whatever experts or resources the board may additionally utilize, this information will assist the board in making its appropriate determinations.

For their thoughtful development of this model framework, the Federation is indebted to its task force members and the boards they serve, either currently or in the recent past:

Salvatore LaRusso, D.C., Task Force Chair – Florida Board of Chiropractic Medicine
Lawrence Davis, D.C. – Chiropractic Physician's Board of Nevada
Hugh Lubkin, D.C. – California Board of Chiropractic Examiners
Gary Pennebaker, D.C. – Minnesota Board of Chiropractic Examiners
Mark Stafford, J.D. – Kansas Board of Healing Arts
Albert Stabile, D.C. – New Jersey State Board of Chiropractic Examiners

As with all Federation documents, continued recommendations for refinements are always welcome. Please contact our executive offices with your ideas.

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FCLB MODEL FRAMEWORK:
Uniform Evaluative Process for Treatments & Devices

Treatment or Device: _____

1. SCOPE OF PRACTICE

1.1 Does the treatment or device fall under this jurisdiction's chiropractic scope of practice as currently written?

☐ YES
☐ NO
☐ UNKNOWN

1.1.1 Cite applicable statute and/or regulations

_____

1.1.2 Cite applicable rulings by the Attorney General or other legal counsel

_____

1.2 Does the treatment or device relate to the practice of chiropractic?
(Is it a service that the licensee offers for the diagnosis/analysis, relief, or correction of a chiropractic condition?

☐ YES
☐ NO
☐ UNKNOWN

Discussion: If the answer to either or both of the above questions is no, the review process may conclude here

1.3 Does the treatment or device ***fall under or overlap with*** another licensed profession's scope of practice?

☐ YES
☐ NO
☐ UNKNOWN

1.3.1 List other profession(s)_____

1.3.2 If there is an overlap, is the licensee required to initiate a referral?

☐ YES
☐ NO
☐ UNKNOWN

1.3.3 If there is an overlap, is the licensee permitted to continue to perform the treatment or use the device (as the overlap does not create a concern that it is out of the chiropractic scope)?

☐ YES
☐ NO
☐ UNKNOWN

2. SAFETY & EFFECTIVENESS

2.1 Is the use of the treatment or device effective, according to ***professionally accepted evidence, specific authority, or tradition***?

☐ YES
☐ NO
☐ UNKNOWN

2.1.1 If yes, cite or describe _____

Discussion: If the answer is no, it may be ***experimental****.*

2.2 How long has the treatment or device been in existence?

_____

2.3 Does the use of the treatment or device pose any safety concerns?

☐ YES
☐ NO
☐ UNKNOWN

2.3.1 List known concerns _____

2.4 Is the device being used in an original, innovative, unique, or off-label manner which is not presently supported by research?

☐ YES
☐ NO
☐ UNKNOWN

3. RECOGNITION / EDUCATIONAL SETTINGS

3.1 Is the treatment or device recognized for utilization by Doctors of Chiropractic in other jurisdictions?

☐ YES
☐ NO
☐ UNKNOWN

3.1.1 How broadly is it recognized? ***(List jurisdictions)***

_____

3.1.2 List any jurisdictions that prohibit or restrict the treatment or device:

3.2. Is the treatment or device recognized as acceptable for utilization ***by other licensed health care professions?***

☐ YES
☐ NO
☐ UNKNOWN

3.3 Is the use of the treatment or device taught in a program approved by the board for CE credit for relicensure – in this jurisdiction or others?

☐ YES
☐ NO
☐ UNKNOWN

3.3.1 List all jurisdictions that have approved this treatment or device for CE for relicensure credit:

3.3.2 What criteria were used to approve the CE credits? ***(I.e., PACE approval, specific board criteria or categorization)***

3.4 Is the use of the treatment or device ***only*** taught in seminars sponsored by the manufacturer, developer, or promoter?

☐ YES
☐ NO
☐ UNKNOWN

3.5 Is the treatment or device ***required or recommended*** by the accreditation Standards of any Councils on Chiropractic Education or their equivalent for the ***core curriculum*** of the doctor of chiropractic program?

Required	***Recommended***
☐ YES	☐ YES
☐ NO	☐ NO
☐ UNKNOWN	☐ UNKNOWN

Discussion: At the time of this publication, there are four CCE's recognized by CCE-International: Australasia, Canada, Europe, and the United States.

3.6 Is the use of the treatment or device taught in any of the accredited doctor of chiropractic programs (DCPs) – in ***either the core curriculum or non-core curriculum?***

Core Curriculum	***Non-Core Curriculum***
☐ YES	☐ YES
☐ NO	☐ NO
☐ UNKNOWN	☐ UNKNOWN

3.6.1 List DCPS / specify core or non-core curriculum:

3.7 Is the use of the treatment or device taught in any ***postgraduate*** programs of any the accredited doctor of chiropractic programs (DCPs)?

☐ YES
☐ NO
☐ UNKNOWN

3.7.1 List participating DCPs

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4. LAWFUL USE OF DEVICES, FOODS AND DIETARY SUPPLEMENTS

(United States only; jurisdictions outside of the United States should check the laws applicable to those jurisdictions.)

4.1 Medical Device

A "medical device" as defined by US federal law, and generally is any instrument, apparatus, or article that is either

(a) intended for use in the diagnose, cure, investigation, treatment or prevention of disease or injury, or

(b) intended to affect the structure or function of the human body other than through use of a drug or food.

Does the professional service include use of a medical device?

☐ YES
☐ NO
☐ UNKNOWN

If "no," go to section 4.2
If "yes," complete section 4.1.1 – 4.1.3

4.1.1 Has the device previously been classified by the US Food & Drug Administration as a Class I, Class II, or Class III medical device?

☐ YES
☐ NO
☐ UNKNOWN

4.1.2 If the device is a Class I or Class II device, the manufacturer and device must be listed and a 510(k) letter on file with the FDA [unless specifically exempted from the 510(k) requirement].

Are advertisements consistent with the 510(k) letter and all labeling requirements?

☐ YES
☐ NO
☐ UNKNOWN

4.1.3 If the device is a Class II or Class III device and special controls have been assigned regarding premarket approval, limitations on distribution, labeling, or other issues, has the licensee complied with those special controls?

☐ YES
☐ NO
☐ UNKNOWN

4.2 Foods (including supplements)

Does the product display the appropriate disclaimers as required by federal law?

☐ YES
☐ NO
☐ UNKNOWN

4.2.1 Are all marketing materials and advertisements of any nature consistent with the labeling requirements for the food or dietary supplement?

☐ YES
☐ NO
☐ UNKNOWN

5. PUBLICATION / MARKETING INFORMATION

5.1 Are there studies (published in recognized, peer-reviewed scientific journals) that uphold the safety and efficacy of the treatment or device?

☐ YES
☐ NO
☐ UNKNOWN

5.1.1 List journal articles, authors, dates

_____

5.1.2 Have copies been provided by proponent for board review?

☐ YES
☐ NO
☐ NOT APPLICABLE

5.2 Is the information being distributed about the treatment or device provided ***solely*** based on data or claims provided by the developer, manufacturer, or promoter?

☐ YES
☐ NO
☐ UNKNOWN

Discussion: If yes, it may be ***experimental***

5.3 Is the information false or misleading or inconsistent with regulatory guidelines?

☐ YES
☐ NO
☐ UNKNOWN

6. COMPETENCY ASSESSMENT

6.1 Are there any examinations offered by any chiropractic regulatory board, the National Board of Chiropractic Examiners, the Canadian Chiropractic Examining Board, or other recognized national or international testing services for chiropractic or other professions that assess knowledge or competency in the use of this treatment or device?

☐ YES
☐ NO
☐ UNKNOWN

6.1.1 List recognized examinations

_____

6.1.2 Describe scope of applicable examinations

_____

6.2 Is there a certification program that demonstrates licensee competence in the use of the treatment or device?

☐ YES
☐ NO
☐ UNKNOWN

6.2.1 Describe the program, including # and scope of training hours, instructor qualifications, other pertinent program details

_____

Discussion: the definition of what constitutes recognition of a "certification program" may vary among regulated jurisdictions.

6.3 List any other ways in which the licensee demonstrates competence in the use of the treatment or device, including understanding of the limits and risks involved, and applicable safety precautions.

_____

7. FINANCIAL ARRANGEMENTS

7.1 Are comprehensive, accurate, and transparent financial arrangements, including incentives and discounts, clearly defined, detailed, and explained to the consumers of that service?

7.1.2 Fees per unit of treatment or service, billing description, CPT code

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.1.3 Methods of billing for such fees

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.1.4 Names of any insurance companies that have agreed to reimburse the practitioner or health maintenance organization with whom the practitioner contracts to provide service:

_____

7.1.5 Whether the practitioner accepts Medicare, medical assistance, or general assistance medical care

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.1.6 Whether the practitioner is willing to accept partial payment, or to waive payment, and under which circumstances

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.1.7 Is there a written agreement, signed and dated by the patient, that delineates the financial terms?

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.2 In utilizing the experimental treatment or device, does or could the licensee engage in abusive or fraudulent billing practices?

- ☐ YES
- ☐ NO
- ☐ UNKNOWN

7.2.1 Describe potential billing concerns:

_____

7.3 If applicable, which codes are being used?

CPT _____

HCPCS _____

7.3.1 Is the use of the device consistent with accepted common procedure terminology?

☐ YES
☐ NO
☐ UNKNOWN

8. SPECIAL CONSIDERATIONS FOR EXPERIMENTAL TREATMENTS AND DEVICES

Definition of Experimental Treatment or Device:

Any professional service that a chiropractic licensee offers for the diagnosis/analysis, relief, or correction of a related health condition as defined by the jurisdiction's scope of practice, when that service does ***not*** meet any of the following criteria:

a) taught in an approved chiropractic college
b) generally accepted by the regulatory board(s) or the ethical and prudent members of the chiropractic profession as being within the standards of care
c) based upon peer-reviewed, scientifically based, and nationally or internationally recognized literature, or other evidence of safety and efficacy.

A board may determine that special provisions shall be required before the treatment or device may be provided to the public. Some of these provisions are listed below as part of the review process. A board may request more information or impose additional criteria to protect the public.

It is generally presumed that a patient or any consumer contemplating diagnosis or treatment has the capacity and right to make a free and informed decision to accept or reject any treatment or use of any device, provided that adequate and accurate information is provided and that opportunities are provided to engage in dialogue and to decline to participate.

8.1 Has the advertising been considered by the board or other regulatory authority to be fraudulent, deceptive or misleading?

☐ YES
☐ NO
☐ UNKNOWN

8.2 In utilizing the experimental treatment or device, does or could the licensee's conduct deceive, defraud or mislead the public?

☐ YES
☐ NO
☐ UNKNOWN

8.3 In utilizing the experimental treatment or device, does or could the licensee harm the public or demonstrate a willful or careless disregard for the health, welfare, or safety of the public?

☐ YES
☐ NO
☐ UNKNOWN

8.4 Are advertised statements accurate that promote the degree, training, experience or other qualifications of the licensee regarding the experimental treatment or device?

☐ YES
☐ NO
☐ UNKNOWN

8.5 Where appropriate and permitted by law, has the following statement been included in promotional materials?

THE **[Name of Chiropractic Board}** HAS NOT ADOPTED ANY EDUCATIONAL AND TRAINING STANDARDS FOR **[Name of Treatment or Device]** THIS STATEMENT IS FOR INFORMATION PURPOSES ONLY.

☐ YES
☐ NO
☐ UNKNOWN

8.6 Is there a brief summary, in plain language, of the theoretical approach used by the practitioner in providing this experimental treatment to the patient and expected duration of the treatment?

☐ YES
☐ NO
☐ UNKNOWN

8.7 Is there a statement or documented opportunity for the patient to refuse the services or treatment?

☐ YES
☐ NO
☐ UNKNOWN

8.8 Prior to the provision of any service or treatment, is there a written statement that the patient must sign, attesting that the patient has read, understands, and agrees with the terms set forth, and that it is understood that the treatment or device is experimental in nature?

☐ YES
☐ NO
☐ UNKNOWN

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WORKSHEET SUMMARY - Regulatory Board Conclusions

Treatment or Device:

_____

1. Scope of Practice Issues

2. Safety & Effectiveness

3. Recognition / Educational Settings

4. Lawful Use of Devices, Foods and Dietary Supplements

5. Publication / Marketing Information

6. Competency Assessment

7. Financial Arrangements

8. Special Considerations for Experimental Treatments and Devices